



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,640	12/31/2003	Lawrence M. Boyd	1842-0021	9392
28078	7590	03/29/2010		
MAGINOT, MOORE & BECK, LLP			EXAMINER	
CHASE TOWER			HARVEY, JULIANNA NANCY	
111 MONUMENT CIRCLE			ART UNIT	PAPER NUMBER
SUITE 3250			3733	
INDIANAPOLIS, IN 46204				
		MAIL DATE	DELIVERY MODE	
		03/29/2010	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/749,640	BOYD ET AL.
	<b>Examiner</b>	Art Unit 3733
	Julianne N. Harvey	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 03 December 2009.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 37,38,41-45 and 54-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 37,38 and 41-45 is/are allowed.
- 6) Claim(s) 54-59 is/are rejected.
- 7) Claim(s) 59 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 3, 2009 has been entered.

***Claim Rejections - 35 USC § 112***

The previous rejection of claims 54-59 is withdrawn in view of Applicant's amendments.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Justis et al. (US 6,293,949 B1) in view of Drewry et al. (US 2003/0083657 A1).  
Regarding **claim 54**, Justis et al. disclose a method for dynamic stabilization of a motion

segment of the spine comprising the steps of: coupling a dynamic stabilization system (20) across the motion segment (see Fig. 1) that permits substantially normal loading patterns on the disc by emulating substantially normal movement of the motion segment in the A/P plane in both directions during normal flexion and extension (col. 1, lines 58-62; col. 7, line 56 through col. 8, line 11 – note that Justis et al. indicate that the system emulates substantially normal movement of the motion segment during flexion and extension – based on the language of the claim, which indicates that emulating substantially normal movement permits substantially normal loading, the examiner is taking the position that the Justis et al. system permits substantially normal loading patterns on the disc because it emulates substantially normal movement). Regarding **claim 58**, Justis et al. disclose that the step of coupling a dynamic stabilization system includes providing a center of rotation of the motion segment that is located substantially at the posterior surface of the pedicle of the vertebrae of such segment (Fig. 2 of Justis et al. show that the system 20 is implanted such that the plate 22 is directly contacting the vertebrae – Applicant's Fig. 3 shows that, when a flexible device is secured to the motion segment, the center of rotation is located parallel to the flexible portion of the device (CR<sub>R</sub> when using Applicant's flexible screws; CR<sub>F</sub> when using a flexible plate spaced from the vertebrae; CR<sub>I</sub> when using spinous process wires) – because the Justis et al. plate directly contacts the vertebrae, and is not spaced from the vertebrae, the examiner is taking the position that the center of rotation would be approximately CR<sub>R</sub> and thus the Justis et al. system meets the claim limitations).

Regarding **claim 54**, Justis et al. fail to disclose introducing a device into an

intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment. Drewry et al. teach that the use of artificial disc devices (which would partially maintain or restore the natural motion of the disc) in conjunction with external stabilization devices (e.g., rods and plates) is advantageous (para. 0002). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Justis et al. method such that it also includes introducing a device into an intervertebral space to at least partially maintain or restore the natural motion of the disc at the motion segment, as suggested by Drewry et al., as the use of artificial disc devices in conjunction with external stabilization devices is advantageous.

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Justis et al. (US 6,293,949 B1) and Drewry et al. (US 2003/0083657 A1) as applied to claim 54 above, and further in view of Bao et al. (US 5,534,028 A). Justis et al. and Drewry et al. teach the claimed invention except that that the step of introducing a device includes introducing a device for replacing or augmenting the nucleus pulposus of the intervertebral disc (**claim 55**), that the step of introducing a device includes introducing a polymeric prosthesis which exhibits physical properties similar to the natural nucleus pulposus (**claim 56**), and that the polymeric prosthesis is formed from a hydrogel (**claim 57**). Bao et al. teach a prosthetic nucleus pulposus made of hydrogel, a polymer, that has physical properties that are substantially similar to the physical properties of a natural nucleus pulposus (col. 3, lines 13-24). It would have been obvious to one of ordinary skill in the art to further modify the Justis et al. method such that the disc replacement is the Bao et al. prosthetic nucleus pulposus (**claims 55-57**)

as such a prosthesis would allow for partial disc replacement as some situations may only require replacement of the nucleus pulposus.

***Allowable Subject Matter***

Claims 37, 38, and 41-45 are allowed.

Claim 59 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julianna N. Harvey whose telephone number is 571-270-3815. The examiner can normally be reached on Mon. - Fri., 6:30 a.m. - 2:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. N. H./  
Examiner, Art Unit 3733  
/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733